Joseph E. Kernan, Governor
State of Indiana

Office of Medicaid Policy and Planning
402 W. WASHINGTON STREET, ROOM W382

To: Members, Health Finance Commission

From: Melanie Bella
Assistant Secretary, Office of Medicaid Policy and Planning

Date: September 30, 2004

Re: Report mandated by HEA 1251, "Returned Medications"

The Office of Medicaid Policy and Planning (OMPP) is pleased to provide the Commission with this report mandated by HEA No. 1251 of the 2004 legislative session of the Indiana General Assembly. The enclosed report focuses on processes used by Indiana Medicaid pharmacy providers in accepting Medicaid-reimbursed medications back from long term care facilities to which the medications were dispensed, and processes that providers are to use in crediting those medications back to the Program. We welcome all comments and suggestions that the Commission may have, and hope that you find this report both informative and instructive.

Joseph E. Kernan, Governor
State of Indiana

Office of Medicaid Policy and Planning
402 W. WASHINGTON STREET, ROOM W382

REPORT TO THE HEALTH FINANCE COMMISSION

CREDITING OF MEDICAID-REIMBURSED MEDICATIONS RETURNED FROM LONG TERM CARE FACILITIES—House Enrolled Act No. 1251, 2004

OFFICE OF MEDICAID POLICY AND PLANNING

September 2004

BACKGROUND: The 2004 session of the Indiana General Assembly passed new statutory provisions as HEA No. 1251, a portion of which addresses the matter of crediting by Indiana Medicaid provider pharmacies of Medicaid-reimbursed medications returned from long term care facilities and subsequently put back in stock for re-dispensing. A copy of the pertinent section of the law is attached for reference ("Attachment 1").

Indiana statute and Board of Pharmacy regulation at IC 25-26-13-25 and 856 IAC 1-21-1 ("Attachment 2" and "Attachment 3", respectively) address circumstances under which unused medications *may* be returned to the pharmacy that dispensed them. Key provisions are:

(1.) that the acceptance of returned medications is optional on the part of the pharmacy provider and is subject to the pharmacist's professional judgment,
(2.) that the medications can be returned to only the pharmacy that dispensed them, and
(3.) that the medications can be returned only if dispensed to a long term care facility in the manufacturer's unopened package or in unit dose packaging. In addition, controlled substances (e.g., narcotics, drugs with a high potential for abuse) cannot be returned.

Realizing that since by law the acceptance of returned medications is optional on the part of the pharmacy, and that acceptance of the medication and crediting to Medicaid is not likely to occur unless the crediting process is straightforward and easy, the Medicaid program in June of 1990 issued a provider bulletin that established procedures that minimize the administrative burden on the part of the pharmacy provider. The program has long-standing policy and operational procedures expressed in provider manuals; copies of the relevant sections are attached ("Attachment 4").

OMPP ACTIVITIES SUBSEQUENT TO HEA NO. 1251: In response to the returned medication-related provisions of HEA No. 1251, OMPP formed an internal working group to address the matter. The working group was comprised of OMPP administrative staff and staff of contractors involved with processing of pharmacy claims and adjustment requests (i.e., EDS, OMPP's fiscal agent contractor; ACS, OMPP's pharmacy benefits manager; and Myers & Stauffer, which is active in both pharmacy and nursing facility policy-related matters). OMPP sent letters ("Attachment 5") to the organized pharmacy associations (Indiana Pharmacists Alliance/Community Pharmacies of Indiana; Indiana Retail Council; Indiana Long Term Care Pharmacy Alliance) with whom we generally consult on Medicaid pharmacy policy matters, seeking their input on the subject provision of HEA No. 1251. OMPP and the parties involved with crediting of returned medications then met for purposes of discussing the returned medication process and gathering the comments and suggestions related to the crediting of returned medications.

The comments and recommendations that resulted from the July 12, 2004 meeting are contained in a post-meeting summary document ("Attachment 6") provided by the Long Term Care Pharmacists Alliance (LTCPA). Two points raised by LTCPA pertain to reimbursement and the Health Insurance Portability and Accountability Act (HIPAA).

The LTCPA believes that pharmacy providers should be reimbursed $11.00 for each crediting transaction that they file. Second, an issue was raised in essence contending that provisions of HIPAA precluded providers from utilizing the established and long-standing system of crediting the program for medications returned from long term care facilities and subsequently re-dispensed. This was of particular concern to OMPP, since OMPP greatly relies on providers to accept and credit the tax-funded medications whenever possible to do so.

FSSA Office of General Counsel staff were asked to review the referenced HIPAA-related document, and having done so issued the attached opinion on the matter ("Attachment 7"). Given that the Office of General Counsel opinion did not concur with the expressed premise that crediting Medicaid-reimbursed medications returned from long term care facilities violated HIPAA, OMPP deemed it advisable to reassure providers that the long-standing policies in that regard remain valid and in effect. At the time of issuance of this report, the provider communication is scheduled to be released the week of October 4, 2004.

SCOPE OF CREDITING: Pharmacies that service nursing facilities have claimed that they are crediting returned medications via on-line transactions. It should be noted that such pharmacies are highly computerized and consequently prefer to not utilize paper-based crediting. Unfortunately, the lack of an electronic claims transmission standard to identify transactions as returned medication credits, per se, effectively precludes our ability to conclusively identify the actual scope of such transactions. A previous estimate based on 2002 adjustment request data (from paper forms) revealed crediting activity of approximately $1 million per year (state and federal shares combined). In order to better understand the level of crediting, however, we are currently considering systems enhancements to identify electronic crediting transactions solely attributable to returned medications.

FUTURE PLANS: As this initiative was unfolding at the State level, the Medicare Modernization Act of 2003 (MMA)[1] was unfolding. Although highly complex, the MMA provides that as of January 1, 2006, Medicare will provide a prescription drug benefit. The benefit, referred to as Part D, will cover the dual eligibles (those individuals on both Medicaid and Medicare) for whom the state has been providing pharmacy benefits. This will have a significant impact on the dual eligibles residing in long term care facilities. As such, it will impact this issue of returned medications since prescription drug plans, rather than Medicaid, will be providing the pharmacy benefit. Medicaid, however, will still be required to fund a significant portion of the expenditures spent on the prescription drugs for the dual eligibles In the interim as this unfolds, OMPP will continue to work with both long term care facility and pharmacy providers to ensure that the existing system of returning and crediting the program for Medicaid-reimbursed medications is as streamlined and easy-to-use as possible. OMPP and its contractors meet on a monthly basis with representatives of the Indiana Pharmacists Alliance/Community Pharmacies of Indiana, and on a periodic basis with representatives of the Indiana Retail Council and Indiana Long Term Care Pharmacy Alliance, as well. OMPP is committed to maintaining open dialogue with these pharmacy provider interests in order to ensure that, while still possible to do so under Indiana Medicaid, crediting of Medicaid-reimbursed medications

returned to pharmacies from long term care facilities is maximized.

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[1] Public Law Number 108-173, signed December 8, 2003

ATTACHMENT 1

Source: House Enrolled Act No. 1251

SECTION 6. [EFFECTIVE JULY 1, 2004] **(a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established by IC 12-8-6-1.**

(b) Before January 1, 2005, the office shall review the process of returning unused medication under IC 25-26-13-25, as amended by this act, and the process of reimbursing the office for unused medication of a Medicaid recipient. The office may consider in the office's review information provided by pharmacies that provide long term care pharmacy services. Beginning December 31, 2004, the office may review the process of returning unused medication when the office determines that a review is necessary.

(c) Before October 1, 2004, the office shall provide any information gathered under subsection (b) to the health finance commission established by IC 2-5-23-3. Before November 1, 2004, the health finance commission shall review the process of returning unused medication under IC 25-26-13-25, including the reimbursement to the office for the unused medication of a Medicaid recipient.

(d) This section expires December 31, 2009.

ATTACHMENT 2

Source: IC 25-26-13-25

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient:

(A) residing in an institutional facility (as defined in 856 IAC 1-28.1-1(6)); or

(B) in a hospice program under IC 16-25;

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in section 17 of this chapter).

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under this section.

(k) A pharmacist who violates subsection (c) commits a Class A infraction.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.239-1989, SEC.1; P.L.33-1993, SEC.46; P.L.188-1995, SEC.6; P.L.187-1999, SEC.5; P.L.270-2001, SEC.4; P.L.288-2001, SEC.4; P.L.1-2002, SEC.98; P.L.182-2003, SEC.4; P.L.97-2004, SEC.95; P.L.75-2004, SEC.2.

ATTACHMENT 3

Source: 856 IAC 1-21-1

856 IAC 1-21-1 Resale of returned substances

Authority: IC 25-26-13-4

Affected: IC 25-26-13-25

Sec. 1. (a) This section implements and interprets IC 25-26-13-25(h) concerning the resale or redistribution of medications.

(b) For a medication to have been properly stored and securely maintained according to sound pharmacy practices, the storage and administration of medications in the institutional facility must be under the immediate control of licensed nursing personnel.

(c) If the medication was originally packaged by the dispensing pharmacy, it cannot be resold or redistributed unless:

(1) the medication has been repackaged into unit-dose packaging using packaging materials that meets Class A or Class B standards, found in the United States Pharmacopeia (U.S.P.), page 1574, published by the United States Pharmacopeia, 22nd Revision, January 1, 1990, United States Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, which standards are incorporated herein by reference; and

(2) the repackaging process complies with the standards as found in the "Proper Treatment of Products Subjected to Additional Manipulations, Section 1191" of the United States Pharmacopeia, page 1705, 22nd Revision, 1990, which section is incorporated herein by reference.

(d) A medication repackaged under the provisions of subsection (c) shall be labeled with an expiration date of not greater than one (1) year until the manufacturer's expiration date, whichever is earlier. *(Indiana Board of Pharmacy; Reg 21, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 128; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1334)*

ATTACHMENT 4

Source: Chapter 9--Indiana Medicaid Pharmacy Provider Manual

Returned Medications

State laws *IC 25-26-13-25(h)* and *(i); 856 IAC 1-21-1 allow* for the return of medications from long term care facilities under certain circumstances to the pharmacy that dispensed the medications.
Note well: *Medications returned to the dispensing pharmacy that are put back in stock for re-dispensing* ***must*** *be credited to the program within 30 days of being returned to the pharmacy.*

To credit the program, providers submit a credit request for the amount of the returned medication, less any applicable dispensing fee. This amount is applied against future payments. The credited amount is posted to the provider remittance advice, and totals on the *Provider 1099 Summary Report* are adjusted. *Chapter 11: Paid Claim Adjustment Procedures* contains specific procedures for crediting the program for returned medications.
The following information about returned medications applies to crediting the program:
• Legend drug claims – Pharmacy providers are allowed to retain the dispensing fee corresponding to the claim being credited. Providers must *prorate* the amount of the credit based on the amount reimbursed, less the dispensing fee.
• Non-legend drug claims – Providers *prorate* the credit based on the total amount reimbursed by the program for the particular claim.
• Returned drugs that are re-dispensed – Any IHCP-reimbursed medication that is returned and redispensed must be credited to the program by the pharmacy within 30 days of its return. Adherence to this requirement is monitored by provider audits.
• Maintenance of reimbursement records – Providers must maintain records, suitable for IHCP audit purposes, of returned medications and the associated credit. The records must clearly substantiate the provider credit practices.

Source: CHAPTER 11—Paid Claim Adjustment Procedures

Medications Returned from Long-Term Care Facilities

Medications returned from long-term care facilities to the dispensing pharmacy, in accordance with applicable law, which are subsequently redispensed, must be credited. To credit these returned medications, providers should submit to ACS a request for a credit corresponding to the amount paid for the returned medication, less any applicable dispensing fee. This amount is set up as a non-claim-specific accounts receivable to be applied against future payments. The credited amount is posted to the provider RA or the 835 – *Health Care Claim Payment/Advice* electronic transaction (835) and the Provider 1099 Summary.

ATTACHMENT 5

Joseph E. Kernan, Governor
State of Indiana

Office of Medicaid Policy and Planning
402 W. WASHINGTON STREET, ROOM W382
INDIANAPOLIS, IN 46204-2739

"People helping people help themselves"

May 24, 2004

(ADDRESSEE)

Dear ----------;

As you are likely aware, section 6 of HEA 1251 (extract enclosed) from the last legislative session requires OMPP to review the process of returning unused medications under IC 25-26-13-25 before January 1, 2005. Further, by October 1, 2004, OMPP is to provide the Health Finance Commission with information gathered under subsection (b) of the cite referenced above. Although the bill does not take effect until July 1, the importance of this matter and the October 1 time frame for completion of the work and reporting compels us to start work on it now. Given the key role played by members of Indiana Long Term Care Pharmacy Alliance, the IPA/CPI, and the Indiana Retail Council in returning medications for which return is possible, we are seeking input from each organization regarding this matter.

We anticipate that it may have been the intent of the statute to determine ways to maximize the crediting of medications by pharmacies when, in accordance with current law, medications are returned to the pharmacy. In that light, we would appreciate your input on the following:

- Are there process steps that you would recommend we consider adding that would facilitate providers returning the medications to stock and crediting Medicaid for them.

- Are there parts of the current process that you would recommend we eliminate or modify that would facilitate providers returning the medications to stock and crediting Medicaid for them.
- Are there any other suggested means by which we could enhance existing processes for accepting medications and crediting Medicaid for them that would improve the participation rate?

To assist you in having the proper context for commenting back to us, we are also enclosing a copy of provider manual text that sets forth the current requirements and procedures for crediting returned medications. We believe that your input in this matter is crucial to what will ultimately be provided to the Health Finance Commission, and in that regard we respectfully ask that you provide us with your written comments by no later than June 30. Hopefully, this time frame will allow you to receive input from your members that are involved in receiving returned medications.

Should you have any questions regarding this letter, please contact Mr. Marc Shirley, RPh of OMPP staff. He can be reached at (local) 317 232-4343 or by e-mail at mshirley@fssa.state.in.us.

Thank you in advance for your comments. We appreciate your partnership in these and other efforts as well as the services your members provide to Indiana Medicaid.

Sincerely,

Melanie Bella
Assistant Secretary

Enclosures (2)

Cc: Mike Sharp, RPh--ACS
Jared Duzan--Myers & Stauffer
Pat Nolting--OMPP
Marc Shirley, RPh--OMPP

Attachment 6

Tim Vordenbaumen
Omnicare Government Affairs

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December 16, 2004

Mr. Marc Shirley, R. Ph.
Office of Medicaid Policy and Planning
402 W. Washington Street
Indianapolis, IN 46204

Dear Mr. Shirley:

Thank you for taking time to meet with us on July 12th. I am sorry that I have taken so long to follow up on the issues that we discussed. This will also respond to Ms. Bella's letter of May 24th.

There are, from our perspective, two significant issues. The process for issuing credit to the agency must be electronic and HIPAA compliant. At this time an electronic transaction is problematic. I have attached a memo prepared by our legal counsel, PattonBoggs that fully discusses this issue and the legal requirement to provide an electronic transaction.

Secondly, a return transaction is unlike that of dispensing and payment of a typical dispensing fee to recover and reuse drugs is well below the costs incurred by the pharmacy. We believe that these costs are about $11.00 per transaction. We will be happy to provide appropriate documentation in this regard as the process moves forward.

I have also attached a copy of the LTCPA policy regarding return and reuse. Once the electronic process is available we will be happy to work with regarding implementation of a return program.

Sincerely,

Vice President
CC: Melanie Bella
Pat McGuffey
IN_LTCPA

Return and Reuse of Nursing Home Drugs

Background/Current Law and Regulations: Some states require long-term care (LTC) pharmacy providers to accept and process unused nursing home drugs for credit to the state Medicaid agency. The regulations that implement this policy vary from state-to-state and are further limited by DEA and FDA guidelines, as well as state boards of pharmacy regulations. As state budgets come under increased pressure we expect states to look more closely as implementing return and reuse policies, either by regulatory action or by statute.

The vast majority of states make no distinction between LTC and retail in their reimbursement policies in the Medicaid program. However, retail establishments have long been exempt from any requirement to accept unused drugs because of the absence of any verifiable chain of custody and assurance that the drugs have not been adulterated. This makes LTC pharmacy the only entity to which return and reuse regulations apply.

The National Council for Prescription Drug Plans (NCPDP) has set specific standard definitions for transaction code fields used for pharmacy claims processing. With the implementation of the HIPAA regulations, HHS has adopted the NCPDP 5.1 Code Set as that standard. The NCPDP 5.1 Code Set currently has no code available for processing a "credit" of a returned drug. There is a transaction process for reversing a prescription that was mistakenly filled or never dispensed. Some Medicaid fiscal intermediaries are using these reversal codes outside of the standard definitions. This suggests that states enforcing return and reuse regulations are using inappropriate codes for processing these returns.

In 2003, NCPDP formed a Long Term Care (LTC) Task Group to deal with this issue. This LTC Task Group is working with LTC pharmacy providers, fiscal intermediaries and pharmacy software vendors to develop a proper return transaction code set standard. Until the new code set is adopted, LTCPA must challenge states under provisions of the HIPAA regulation related to the improper use of electronic codes. We recommend states wait for the new code sets to be developed before insisting on the improper processing of returned medications.

Principles for Return and Reuse of Unused Nursing Home Drugs

- **Processing drug returns costs more than dispensing**: Contrary to popular belief, processing returned drugs is not simply dispensing in reverse. The process by which drugs are processed for return and credit consists of several elements that differ from the process of dispensing.

    - Pharmacies receiving inventory from wholesalers and manufacturers track inventory largely through automated processes. Returned drugs require manual counting and documentation by trained pharmacy staff.
    - Returned drugs must be inspected by a qualified pharmacist to determine which drugs are suitable for return. Drugs deemed unsafe must be inventoried, destroyed, and the destruction must be documented.
    - The reimbursement status of the person for whom the unused drugs were originally dispensed may not always be clear. Often, the dispensing pharmacy may not know to whom the services are to be billed until the month following the period in which the drugs were dispensed. Currently, these determinations must be performed by trained staff using manual processes in order to determine the payer to whom the credit should be issued.

- Dispensing prescription drugs is tracked by the pharmacy by automated computer systems. Processing a returned drug for credit requires manual tracking because the original claim must be located, reversed, adjusted and re-billed. There is no clear record of the credit.
- LTC pharmacies are generally high-volume enterprises, processing thousands of prescriptions per day. In order to accommodate the additional task of processing credits, the LTC pharmacy may need to be re-designed.

- **Re-stocking fees must be adequate to cover the additional costs**: A re-stocking fee, like a dispensing fee, is intended to cover the professional costs of providing service. As such, the re-stocking fee must be adequate to cover the cost as described above.

- **Credits should be limited to high-cost drugs**: Because of the high cost of processing unused drugs for credit, mandatory returns should be limited to a small number of high cost drugs for which the process produces meaningful savings.

- **Returns should be limited to full cards or original unit dose packages:** The process of stripping unused medicines from heat-sealed cards and reassembling them into new heat-sealed packages involves significant labor and subjects the drugs to an environmental stress that will reduce the shelf life of a drug. Manufacturers do not typically provide the FDA with information on the potency of drugs exposed to this type of repeated heat stress.

- **Claims reversal should be done through batch processing** Claims reversals should be performed in a manner that promotes efficiency. Rather than require pharmacies to access the original claim, reverse, adjust, and re-bill the claim reflecting the credit, a system that accommodates batch processing of returns needs to be developed. Electronic coding standards required by HIPAA currently contain no codes for issuing a credit to any payer. We recommend that states not implement mandatory return credits until the coding system can accommodate an efficient procedure.

- **States should permit seven-day initial fills upon nursing home admission:** The majority of medication adjustments for nursing home patients occur within the first week of admission to the facility. By limiting the dispensing of drugs to smaller quantities during this period, there will be less waste to process, resulting in savings to the Medicaid program. The LTC pharmacy should not be bound by a limit on the dispensing fee for subsequent refills during this period.

- **States should provide regulatory guidance through the board of pharmacy**: The limitations on the types of drugs eligible for return credit should be subject to the professional oversight of the state board of pharmacy for such obvious limits as:

    - Pharmacies should not be required to return refrigerated drugs, drugs that potentially adulterated, controlled substances and drugs that are within 120 days of labeled expiration date.
    - Pharmacists should be empowered to use their professional judgment in determining which drugs are acceptable for re-packaging and return to stock.
    - Drug returns should be returned only to the dispensing pharmacy, in tamper-evident packaging, where information is available to identify products that have been recalled and when stored and transferred properly by the nursing facility.
    - Pharmacies should follow the USP-NF, section 1146 "Packaging Practice-Repackaging a Single Oral Drug Product into a Unit-Dose Container". Blister packaging or bingo cards may not be accepted by the pharmacy for return and reuse unless the entire unused package is returned and in the pharmacist judgement that same package can be re-dispensed without removing medications from the package.

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MEMORANDUM

To: State Medicaid Departments
Date: June 2004
Subject: State Medicaid Return and Reuse Rules and the HIPAA Regulations

This memorandum addresses the issue of whether states can undertake return (with or without reuse) programs prior to the NCPDP creation of a specific transaction code set for such processes. The memorandum concludes that states cannot do so without violating HIPAA and its implementing regulations.

I. Background

Some state Medicaid agencies require long-term care (LTC) pharmacies to accept and process unused nursing home drugs and credit the Medicaid program. The regulations implementing these return and reuse requirements vary from state to state. LTC pharmacies have face difficult and costly compliance efforts related to return and reuse laws. Many states insist that LTC pharmacies manually calculate the drugs qualifying for return and reuse. This is a violation of the HIPAA Transaction Regulations which, effective October 16, 2003, required Medicaid agencies to accept electronic transactions using the standard code sets adopted by the Centers for Medicare and Medicaid Services (CMS). As of that date, LTC pharmacies and the State Medicaid agencies were obligated to exchange data using the CMS' adopted NCPDP code set, Version 5.1.

. Other states (the majority) require LTC pharmacies to use EDI when processing return and reuse drugs. Those states that utilize electronic transactions, however, are using codes that are not appropriate to the transaction. As explained below, version 5.1 of the NCPDP code set does not contain a code that recognizes return and reuse requirements. For example, some states have characterized the return and reuse transaction as an "incentive." "Incentive" codes do not accurately represent what LTC pharmacies are doing under the return and reuse laws. The use of inappropriate codes also is a violation of the HIPAA regulations

Certain LTC pharmacy providers are working to establish a more appropriate process. Until that process is complete, however, and the NCPDP adopts a "return" specific code, states may not misuse the existing NCPDP codes for processing returns. Stated differently, all state return programs must be suspended pending the NCPDP's completion of its code revision.

II. The HIPAA Code Sets

CMS published the Final HIPAA Transaction Regulation on August 17, 2000. 65 Fed. Reg. 50312 (2000). Under this Regulation, any entity that conducts one of the HIPAA standard transactions using electronic media with another covered entity (or within its own entity) must conduct the transaction as a standard transaction. *Id.* at 50317. Health plans must conduct transactions as standard transactions if another entity requests that they do so. 45 C.F.R. § 162.925(a). Health plans may not delay or reject a standard transaction. *Id.*

In this Regulation, CMS adopted standards for eight electronic transactions and six code sets. These transactions are:

- Health Care Claims or Equivalence Encounter Information;
- Eligibility for a Health Plan;
- Referral Certification and Authorization;
- Health Care Claim Status;
- Enrollment and Disenrollment in a Health Plan;
- Health Care Payment and Remittance Advice;
- Health Plan Premium Payments; and
- Coordination of Benefits.

Id.

The Regulation requires LTC pharmacies to use the NCPDP codes, including the Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1). 68 Fed. Reg. 8381 (2003).

III. Modifying Codes Through the NCPDP

A covered entity may seek to modify the adopted standards using the process proposed by using the process that combines CMS requirements with those of the Designated Standard Maintenance Organizations (DSMOs) managing the code sets. Once the DSMO completes its work, CMS must promulgate a rule adopting the new code set.

CMS designated the NCPDP as a DSMO, *see* 67 Fed. Reg. at 38052, and the NCPDP has authority to respond to Change Requests for pharmacy code sets. Generally speaking, the NCPDP is bound by the requirements of the Memorandum of Understanding (MOU) it signed with CMS. Under this MOU, the NCPDP must (1) maintain the adopted standards and (2) receive and process requests for adopting a new standard or modifying an adopted standard. 45 C.F.R. § 162.910(a). The process must (1) be open to the public; (2) be coordinated with other DSMOs; (3) include an appeals process for the requestor of the proposed modification or a DSMO that participated in the review or proposed the new standard; (4) provide for an expedited process to address content needs identified within the industry; and (5) include submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS). *Id.* at § 162.910(c). The Secretary may modify the standards as necessary and no more than once a year. HIPAA, § 1174. In adopting modifications, the Secretary will seek guidance from Standard Setting Organizations (SSOs), such as the NCPDP.

As a DSMO, the NCPDP has established its own processes for modifying codes and incorporated the CMS MOU requirements into it. Any interested party may submit a HIPAA change request for a new or modified code in one of two ways – (1) directly through the NCPDP's own process or (2) through the DSMO Change Request System. Beginning in 2003, the Long Term Care Pharmacy Alliance began working with the NCPDP to create and implement a code for return and reuse. The process, however, is not complete, and is not expected to be complete until mid-2005, at earliest.

IV. Implications of the HIPAA Transaction Regulation for Return and Reuse Transactions

Because the HIPAA Transaction Regulation applies to the return and reuse transactions, states are presently unable to the Regulation mandates an interruption in the implementation of the return and reuse laws. The HIPAA Transaction Regulation applies in this context because both the state Medicaid agencies and pharmacies are covered entities. The Medicaid agencies are "health plans" and must, at least, have the capacity to use the electronic transactions and code sets. *See* 45 C.F.R. § 162.925; *see also* 65 Fed. Reg. at 50314. Because both the Medicaid Agencies and the LTC pharmacies are covered entities their EDI submissions must comply with the HIPAA Transaction Regulation.

Compliance with the HIPAA Transaction Regulation means that the state Medicaid agencies must be capable of receiving, processing, and sending standard transactions electronically. 45 C.F.R. § 162.925. These agencies must also have the capacity to process standard claim, encounter, enrollment, eligibility, remittance advice, and other transactions. *Id*. The HIPAA Transaction Regulation does not permit the use of local codes. Only those codes adopted within the Regulation may be used. Because no code exists for return and reuse, however, state Medicaid agencies cannot adopt self-made codes for the transaction or misuse other regulations.

V. Conclusion

The HIPAA-required NCPDP version 5.1 today does not contain a specific code for return of prescription drugs. States that are requiring the return process to be handled manually are violating the HIPAA requirements. Similarly, those states that are using other codes for purposes of tracking returns of drugs to LTC pharmacies are also in violation of the law.

States must suspend their drug return programs with LTC pharmacies until such time as the NCPDP, through its regular system, adopts a “return” code and CMS enacts that Code into its regulations.

ATTACHMENT 7

FAMILY AND SOCIAL SERVICES ADMINISTRATION
OFFICE OF GENERAL COUNSEL
MEMORANDUM

To: Marc Shirley

From: Scott Linneweber

Subject: HIPAA and Returned Drugs in Nursing Facility Pharmacies

Date: August 24, 2004

CC: Catherine Rudd

QUESTION PRESENTED

Whether OMPP can require nursing facility pharmacies to continue "return and reuse" transactions where no "return and reuse" code has been adopted by the Department of Health and Human Services (HHS)?

BRIEF ANSWER

Because HIPAA language and federal regulations only require regulated entities to follow standard transactions where those transactions have been adopted by HHS, OMPP can require nursing facility pharmacies to continue "return and reuse" transactions.

STATEMENT OF THE FACTS

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was introduced "to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, . . . to improve access to long-term care services and coverage, [and] to simplify the administration of health insurance . . . ." Pub. L. 104-191 (1996). HIPAA standardized certain transactions within the health insurance milieu so that health information could easily be exchanged electronically. As part of the administrative simplification aspects of HIPAA, code sets, standards, and transactions were defined and incorporated into HIPAA; where transactions are standardized, regulated entities are required to use standardized elements with some exceptions. See generally 42 U.S.C. § 1320d-7 (2004); 45 C.F.R. §16.925 (2004). The National Council for Prescription Drug Programs (NCPDP) is charged with creating retail pharmacy implementation standards. Id. at §162.920.

Pharmacies are able to accept and reuse returned and unused medications that have been dispensed to patients residing in institutional facilities or in a hospice program.

Ind. Code § 25-26-13-25 (i) (2004). The statute requires that the drugs meet certain specific criteria before being reused, and the pharmacist may use his professional judgment in deciding whether to accept medication for return at all. Ind. Code 25-26-13-25 (i) and (j). In processing returned drugs, Indiana uses a non-claim specific adjustment approach. The state believes that no HIPAA transaction supports this type of adjustment as claim transaction, replacement transaction, and void transactions are unsatisfactory in ensuring proper refund outcomes. OMPP believes it is important for the return and reuse program to continue because the Medicaid program is billed for prescription drugs that are not used due to changes in medical condition including death, discharge, and medication regimen adjustments.

In June of 2004, Patton Boggs sent a memo to state Medicaid departments that concluded that medication return programs violated HIPAA provisions. This conclusion was based on the assertions that 1) the manual calculation of return drugs was not an electronic transaction, and 2) because the electronic transaction code for "return and reuse" had not yet been developed by NCPDP, the use of other codes to define the transaction was inappropriate. A trade organization of affected pharmacies, noting that return and reuse procedures are costly, has proposed all return and reuse programs cease until proper standards are developed.

ANALYSIS

Manual Calculation of Return Drugs

"[T]he focus of HIPAA is on enabling electronic portability, not simply on regulating purely electronic activity." S.C. Med. Ass'n. v. Thompson, 327 F.3d 346, 353 (4th Cir. 2003). In S.C. Med. Ass'n, a group of providers sought to have HIPAA declared unconstitutional. As part of their argument, the providers claimed that HIPAA was intended to only cover electronic records, and that HHS had illegally expanded the scope of the act to cover all forms of information held by covered entities. In upholding the dismissal of the case, the court of appeals held that the transactions described by HIPAA "do not invite the limitation to a purely electronic scheme." Id. The court noted that transactions such as enrollment and disenrollment were not described in terms that "limit[ed] their scope to electronic media."

Pharmacies appear to be arguing that they cannot be ordered by the state to manually calculate return drugs because such a calculation is not an electronic transaction, and HIPAA requires all transactions to be electronic. However, HIPAA does not mandate that all transactions be limited to the electronic media. Rather, HIPAA seeks to "enable health information to be exchanged electronically." Id. Therefore, the fact that pharmacists will have to perform a manual (non-electronic) calculation would not bar pharmacists from performing that calculation for the state.

Absence of NCPDP Code for "Return and Reuse"

"The preeminent canon of statutory interpretation requires us to 'presume that [the] legislature says in a statute what it means and means in a statute what it says there.'"

BedRoc Ltd. v. United States, 124 S. Ct. 1587, 1593 (2004). (quoting Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253-254 (1992)). Statutes are construed so that words are not rendered "meaningless, redundant, or superfluous." United States v. Misc. Firearms, 2004 U.S. App. LEXIS 15022 (7th Cir. 2004). Where a statute is found to have two possible interpretations, "the entire text and structure of the statute [is considered in] determin[ing] its meaning." Id.

The pharmacies maintain that NCPDP has not yet adopted a "return and reuse" code for HIPAA purposes, and until NCPDP does adopt such a code, states may not use their own methods to accomplish the transaction. According to HIPAA, "The Secretary shall adopt standards that . . . establish code sets for such data elements if no code sets for the data elements have been developed." Furthermore, "if a covered entity conducts with another covered entity . . . using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction." 45 C.F.R. § 162.923. Both the state and the pharmacies agree that no code has been established describing the return and reuse function, and as such, the transaction cannot be a standard transaction. The pharmacists maintain that because it cannot be a standard transaction, to perform the transaction would be a HIPAA violation. However, such a reading of HIPAA does not take into account the plain language used in the rules enacted by HHS. HIPAA is more accurately understood as stating that a transaction must be treated as a standard transaction only when the Secretary has adopted a standard for the transaction. Thus the return and reuse transaction need not cease. It may continue for now, and when a standard is adopted, at that point the state and pharmacies must use HHS's adopted standards, transactions, and codes.

The most appropriate interpretation of the questioned HIPAA language is the one that fulfills the purposes of HIPAA and takes into account other provisions in HIPAA. HIPAA was designed in part to eliminate waste. A similar purpose was envisioned when Indiana allowed institutional facilities and hospice programs to return and reuse unused drugs. The lack of a "return and reuse" code does not prevent pharmacists from assisting the federal and state government in eliminating preventable waste in the Medicaid program. Although administrative simplification is also a goal of HIPAA, following the state's proposed course of action is not likely to impede the portability of a Medicaid recipient's health insurance. Furthermore, HIPAA has allowed for exceptions to using standardized codes. Thus, it would not be inappropriate to interpret HIPAA as allowing states flexibility in areas where HHS had not otherwise mandated particular standards – especially where that course of action will prevent the waste of state and federal taxpayer dollars

CONCLUSION

The mere fact that a transaction requires non-electronic actions does not mean that the transaction violates HIPAA standards. The non-adoption by HHS of a "return and reuse" code would allow pharmacists to continue to accept returned drugs from institutional facilities and hospice programs and reuse the drugs. Such a practice is not only allowed but encouraged due to state and federal interests in combating waste in the Medicaid program.